

REMARKS

Amendments

5 Independent claims 1 and 20 have been amended by removal of the
proviso. It is submitted that these amendments can properly be made at this stage of
prosecution, because they render moot the rejection of claims 1 and 20 under 35 U.S.C.
112, do not raise any new issue for consideration by the Examiner, and place the claims
in better condition for any appeal that may be necessary. The proviso was inserted into
10 claims 1 and 20 in the Reply to the previous Office Action in order to ensure that there
was no overlap between the claims of this application and the claims of the issued
parent U.S. Patent No. 6,376,032, and thus to obviate the double patenting rejection.
Since the Examiner rejected the addition of the proviso and maintained the double
patenting rejection, Applicants have decided, in the interests of speedy prosecution, to
15 remove the proviso and to file a terminal disclaimer. Applicants retain the right to
prosecute, in a continuing application, claims that contain the canceled proviso (or a
similar proviso), and the right to argue, in a continuing application, that the double
patenting rejection should be withdrawn.

20 New claims 32 and 33, dependent on claims 1 and 20 respectively, have been
added. They specify that the polymeric matrix of microporous film is composed of
polyethylene, and that the distribution of pore sizes is as set out on page 17, lines 22-
23. Applicants wish to add these claims so that the application contains claims
restricted to microporous films which are substantially the same as the Teslin SP7
25 microporous films used in many of the Examples of the application. It is submitted that
these claims can properly be added at the present stage of prosecution, since they do
not raise any new issue for consideration by the Examiner and place the claims in better
condition for any appeal that may be necessary, their addition having been prompted by
the Examiner's observation that "if the applicant intends to rely on Examples in the
30 specification... to show non-obviousness, the applicant should clearly state how the
Examples... are commensurate in scope with the claims". Applicants believe that all the

claims in the application are patentable having regard to the facts and arguments set out in this and the previous Reply, but wish to be able to argue separately for new claims 32 and 33.

5 Claim 29 has been rewritten in independent form, by incorporating therein the wording of claim 20, with the proviso removed. Claim 29 was rejected only on the ground of double patenting, and in view of the Terminal Disclaimer attached hereto, is believed to be allowable.

10 Claim 15 has been restricted in scope. It is submitted that this amendment can properly be made at the present stage of prosecution, since it does not raise any new issue for consideration by the Examiner and places claim 15 in a form in which its independent patentability can be argued.

15 **The Rejection on the ground of Double Patenting**

 Applicants respectfully traverse the rejection of claims 1-4, 6-8, and 14-16 over U.S. Patent No. 6,376,032 under the judicially created doctrine of double patenting, and the rejection of claims 20-21, 23-25 and 29 under the judicially created doctrine of
20 obviousness-type double patenting, having regard to the Terminal Disclaimer filed herewith.

The Rejections under 35 U.S.C. 102 and 35 U.S.C. 103

25 **Summary of the Invention**

 The invention relates to gas-permeable membranes comprising a microporous film and a polymeric coating on the microporous film, and the use of such membranes as atmosphere control members in packages for respiring biological materials. The
30 claims of the present application are based on Applicants' discovery of the importance of the size and distribution of the pores in the microporous film, in particular the

desirability of using pores that are not too large and not too widely distributed. Page 4, lines 17-25, of the specification reads:

The size and distribution of the pores in the microporous film are important factors. If the pores are too small, the coating polymer tends to form a continuous layer which is either too thin to be durable under routine handling, or too thick to have an acceptable OTR (i.e. oxygen transmission rate). If the pores are too large, the coating polymer may be unable to bridge over them, so that the coating plays little or no part in determining the permeability characteristics of the membrane. This may happen even if the average pore size is relatively low, if the pore have a wide range of sizes; for example the coating polymer may effectively block many of the pores, but still fail to block the larger pores, whose permeability then dominates the permeability of the membrane as a whole.

The application contains two independent claims, claims 1 and 20, which define the discovery set out above in different ways. Both independent claims require that the pores have an average pore size of less than 0.24 micron. However, this requirement is not in itself a sufficient definition, and Applicants do not contend that it is important to the present rejections of the claims.

Claim 1 defines the microporous film as one that has been made by a particular process. Claim 1 reflects the Applicants' discovery that microporous films made by that process (providing they have an average pore size of less than 0.24 microns) inherently have pores of desirable size and distribution.

Claim 20 defines the pore size and distribution of the microporous film directly, by requiring (in addition to an average pore size of less than 0.24 microns) that at least 70% of the pores have a pore size of less than 0.24 micron, less than 20% of the pores have a pore size less than 0.014 micron, and at least 80% of the pores have a pore size less than 0.15 micron.

Summary of the Prior Art

The claims have been rejected over a single reference, U.S. Patent No. 5,160,768 ("Antoon"). Antoon discloses gas-permeable membranes comprising a microporous film which is composed of a polyolefin filled with 40 to 75% of calcium carbonate and which carries a coating thereon of a cured silicone elastomer. Antoon also discloses the use of such gas-permeable membranes as atmosphere control members in packages for respiring biological materials. The microporous films used by Antoon are prepared by process which is completely different from that defined in claim 1. Antoon gives very little information about the size and distribution of the pores in his microporous films, and such information as there is suggests that large pores are more desirable than small pores.

The Rejection of claims 1, 2, 7, 8, 11, 13, 15-16 and 30 under 35 U.S.C. 102, and the rejection of Claims 2-6 under 35 U.S.C. 103

[In the Office Action, the rejection under 35 U.S.C. 103 of claims 2-6 (which define the microporous film by its method of preparation) is discussed together with the rejection under 35 U.S.C. 103 of claims of claims 20-26, 28 and 31 (which define the size and distribution of the pores directly). Applicants believe that the issues will be more correctly considered if the rejection of claims 2-6 under 35 U.S.C. 103 is considered together with the rejection of claims 1, 2, 7, 8, 11, 13, 15-16 and 30 under 35 U.S.C. 102.]

Applicants respectfully traverse the rejection of Claims 1, 2, 7, 8, 11, 13, 15-16 and 30 under 35 U.S.C. 102 as anticipated by Antoon and the rejection of claims 2-6 under 35 U.S.C. 103 as unpatentable over Antoon. Applicants submit, for the reasons set out below, that the claims 4, 5, 6, 15, 30 and 33 are independently patentable, even if the other claims are unpatentable.

Claim 1 is an independent claim, and claims 2-8, 11, 13, 15-16 and 30 are dependent on Claim 1. New Claim 33 is also dependent on Claim 1. Claim 1 (and, therefore, each of claims 2-8, 11, 13, 15-16 and 30 and new Claim 33), requires that the

microporous film has been prepared by passing a continuous sheet comprising a powdered polymer, a filler, and a processing oil through calender rolls to reduce its thickness; treating the calendered sheet with an organic extraction liquid which removes the processing oil; and removing the extraction liquid by steam or water or both. The process used by Antoon to prepare his microporous sheets is quite different. As disclosed in column 4, lines 48-59, of Antoon, it involves casting a sheet of a mixture of a polymer and a filler, and drawing the sheet to effect orientation of the polymer along its longitudinal and transverse axis. During the process, "the polymer pulls away from the filler material causing voids and pores to form in the film matrix". The degree of permeability that results is stated to be "a function of the amount of filler in the polymer, the amount of draw imposed upon the polymer and the temperature at which the drawing is carried out".

The Examiner has not suggested that the process defined in Claim 1 to prepare the microporous sheet is the same as, or obvious having regard to, the process disclosed in Antoon for preparing his microporous sheet.

Applicants believe that the proper legal basis for the rejection under 35 U.S.C. 102 is set out in MPEP 2113, the correctness of which is not disputed. Insofar as the rejection may be understood to differ from MPEP 2113, Applicants believe that the rejection is incorrectly stated.

Applicants accept, therefore, that (so far as the rejections of claims 1, 2, 7, 8, 11, 13, 15-16 and 30 under 35 U.S.C. 102, and of Claims 2-6 under 35 U.S.C. 103, are concerned) the burden is on Applicants to show an unobvious difference between the microporous films defined in the claims and the microporous films disclosed in Antoon.

Applicants submit that that burden is discharged by the Clarke declaration filed with the Reply mailed December 6, 2002, in particular the passages summarized below.

1. Paragraph 9, page 5, lines 1-11.

The voids in the microporous films defined in Claim 1 are produced by an extraction process which produces voids whose shape is substantially the same as the pockets and channels of the processing oil in the polymeric matrix. The voids in Antoon's microporous films are produced in an essentially random fashion by a drawing process which involves sudden violent rupture of the polymeric matrix. As the result, the voids in the microporous films defined in Claim 1 are quite different from the voids in Antoon's microporous films.

2. Paragraph 10, page 5, lines 13-24.

The differences between the voids are reflected in the different pore size characteristics of the resulting microporous films. In particular, microporous films produced by Antoon's process are less consistent in their pore sizes, have a wider range of pore sizes, and have a greater proportion of larger pores. As a result, coated membranes based on microporous films produced by Antoon's process are inferior to coated membranes based on microporous films produced by the process defined in Claim 1. The reason for this appears to be that the larger pores are not blocked (or not completely blocked) by the coating polymer, especially at the low coating weights which are preferred in order to obtain adequate oxygen permeability.

3. Paragraphs 11-12, page 5, line 26, to page 8, line 2.

The specific Examples of Antoon demonstrate that, as would be expected from the novel teaching of the present application, Antoon's coated membranes suffer from the disadvantages that result from a wide range of pore sizes and the presence of substantial proportions of relatively large pores. For example, in Antoon's coated membranes neither the OTR nor the R ratio is a function of the coating weight of the polysiloxane coating polymer, and it is not possible, even at the relatively high coating weights to obtain a coated membrane having an R ratio which fully reflects the R ratio of the coating polymer. By contrast, the specific Examples of the present application make it clear that, when the microporous film has been prepared by the extraction process defined in Claim 1, and has been coated with the same polysiloxane coating polymer as was used

by Antoon, substantially higher R ratios are obtained and there is a progressive reduction in the R ratio of the coated membrane, and a progressive increase in its OTR value, as the coating weight is reduced.

5 In the Office Action, the Examiner states that the Clarke declaration has been considered but is not persuasive, and that Applicants have not "provided evidence to show that the articles are structurally different" or "provided evidence to show the criticality of the claimed average pore size". Applicants believe that the Clarke declaration, in particular the passages summarized above, provides clear evidence to
10 show that the microporous films defined in Claim 1 are structurally different from the microporous films disclosed in Antoon. Applicants also believe that the Clarke declaration, in particular the passages summarized above, provides clear evidence that the identified structural differences are critical to the properties and performance of membranes produced by coating the microporous films with polymers. Applicants do
15 not understand why the Examiner considers that the Applicants should provide evidence to show the criticality of the claimed average pore size. Applicants have not argued, and are not now arguing, that the average pore size of less than 0.24 micron distinguishes the claimed invention from Antoon.

20 If the Examiner maintains a rejection under 35 U.S.C. 102, she is asked to state in detail why she believes

- (i) that the Clarke declaration, in particular the passages noted above fails to provide evidence that there is an unobvious difference between the microporous films prepared by the process defined in Claim 1 and by the process disclosed in
25 Antoon, and
- (ii) that Applicants should provide evidence for the criticality of the average pore size of less than 0.24 micron.

The Office Action makes the following statements in support of the rejection.

(1) "Since Antoon teaches that which appears to be identical to that disclosed by the applicant with respect to permeability, the recited properties not specifically disclosed by Antoon would be inherent".

5 (2) "... the gas-permeable membrane of Antoon is identical to or only slightly different than the gas-permeable membrane prepared by the method of the claim, because both gas-permeable membranes have a microporous polymeric film and a polymeric coating on the microporous film, both have an oxygen permeance (i.e. OTR) of at least 775,000 ml/m².atm.24 hrs (50,000 cc/100 in².atm.24 hrs) and a CO₂ /oxygen permeability ratio (R) of at least 1.5", as
10 required by Applicants' claim 1.

As to Statement (1) above, it is incorrect to state that "Antoon teaches that which appears to be identical to that disclosed by the applicant with respect to permeability". In addition, it is unclear in the context of this rejection, what the Examiner means by "the
15 recited properties". If the Examiner maintains a rejection relying on this Statement (1) she is asked to clarify what is meant by "the recited properties".

Applicants agree that there is an overlap between the OTR and R ratio required by the present claims and the OTR and R ratio stated by Antoon. Thus, Antoon states
20 that the "silicone-coated film must be selected to have a permeability sufficient to allow the type of control required within a reasonable time and an area suitable for the amount of produce being packaged" (col. 4, lines 43-47), and that the gas-permeable membrane has an oxygen permeance of 5000 to 1,000,000, preferably 20,000 to 900,000, cc/100 in².atm.24 hrs and a R ratio of 3 to 6, preferably 4 to 5 (col. 3, lines 16-
25 25, and col. 5, lines 13-16). But that fact does not properly lead to a conclusion that Antoon's teaching is identical to the teaching of the application. The fact of the matter is that the present application contains much detailed teaching which is not to be found in Antoon, in particular the effect of pore size and distribution, as well as other significant variables not mentioned by Antoon.

It is not correct to state that, because two gas-permeable membranes have similar OTR and R ratios, they are identical to, or only slightly different from, each other. Still less is it true to say (as does Statement 2) that because two gas-permeable membranes have OTRs and R ratios above certain levels, they are identical to, or only slightly different from, each other. This is shown by paragraph 6 of the Clarke declaration, which states:

"the OTR and R ratio of a gas permeable membrane can vary widely above the stated minimum values, and this variation can result from the use of microporous films and/or polymeric coatings which differ from each other",

"even when gas-permeable membranes have substantially the same OTR and R ratio, they can be based on substantially different microporous films and/or substantially different polymeric coatings, and

"even when the polymeric coating is the same, gas permeable membranes based on different microporous films can have OTR and R values which are greater than the stated minimum values, but which are widely different from each other".

If the Examiner maintains Statement (2) above as basis for a rejection under 35 U.S.C. 102, she is asked to explain how it can be maintained in view of the passages quoted above from the Clarke declaration.

Independent Patentability of Claims 4, 5, 6, 15, 30 and 33

It is submitted that claims 4, 5, 6, 15, 30 and 33 are independently patentable for the reasons set below.

Claim 4. Claim 4 requires that at least 90% of the pores have a pore size less than 0.24 micron. Antoon does not disclose this feature, and the evidence in paragraph 13 of the Clarke Declaration establishes that microporous films prepared by Antoon's process do not have this feature.

Claim 5. Claim 5 requires that substantially 100% of the pores have a pore size less than 0.24 micron. Antoon does not disclose this feature, and the evidence in

paragraph 13 of the Clarke Declaration establishes that microporous films prepared by Antoon's process do not have this feature.

Claim 6. Claim 6 requires that at least 80% of the pores have a pore size less than 0.15 micron. Antoon does not disclose this feature, and the evidence in paragraph 13 of the Clarke Declaration establishes that microporous films prepared by Antoon's process do not have this feature.

Claim 15. Claim 15 requires that the microporous polymeric film contains pores partially blocked by a polymer having an R ratio of less than 1.3 or by a particulate material. It is clear that Antoon does not disclose such a microporous polymeric film.

Backspace

Claim 30. Claim 30 requires that the filler in the microporous film is a siliceous filler. Antoon makes it clear that his microporous film must contain 40 to 75% of calcium carbonate. This is explicitly stated in the Summary of the Invention (col. 2, lines 48-49), claim 1 (col. 10, lines 9-10) and elsewhere. The Examiner has noted that col. 4, lines 60-67, of Antoon states that "a large number of inorganic materials have been shown to be effective as fillers for effecting void and pore formation", including silica. However, that disclosure is only in the context of a description of "microporous films and the preparation thereof... known in the art" (col. 4, lines 48-49); it is not part of the disclosure of the invention. The likely explanation (and therefore the teaching derived from Antoon by one skilled in the art) for Antoon's explicit choice of calcium carbonate is that microporous films using other fillers are not satisfactory.

Claim 33. Claim 33, which is dependent on claim 30, requires that the polymeric matrix of the microporous film is composed of polyethylene and that the distribution of pore size is as set out in the table forming part of the claim. Thus, claim 33 is substantially restricted to membranes in which the microporous film is the product sold as Teslin SP7, as disclosed on page 17, lines 14-23.

The Rejection of claims 20-26, 28 and 31 under 35 U.S.C. 103

Applicants respectfully traverse the rejection of claims 20-26, 28 and 31 under 35 U.S.C. 103 as obvious over Antoon. [It is noted that the previous section of this Reply discusses the rejection of claims 2-6 under 35 U.S.C. 103.]

Applicants submit, for the reasons set out below, that the claims 21, 22, 23, 31 and 32 are independently patentable, even if the other claims are unpatentable.

The Office Action states that Antoon "fails to teach the recited average pore size and densities of the pores". However, as noted above, Applicants admit that Antoon's microporous films do meet the requirement in Claim 20 that the average pore size is less than 0.24 micron. It would, therefore, be more correct to state that Antoon fails to disclose the requirements of Claim 20 that at least 70% of the pores have a pore size of less than 0.24 micron, less than 20% of the pores have a pore size less than 0.014 micron, and at least 80% of the pores have a pore size less than 0.15 micron, and fails to disclose the further limitations on pore size in claims 21-23.

In support of the rejection under 35 U.S.C. 103, the Office Action states

(3) that, since Antoon teaches a gas-permeable membrane having the OTR and R ratio specified in the claims, "it would have been obvious to one of ordinary skill in the art to have provided the specified pore size and density in the microporous film", and

(4) that "since Antoon teaches that which appears to be identical to that disclosed by the applicant with respect to permeability, the recited properties not specifically disclosed by Antoon would be inherent".

The first of these statements, Statement (3), presupposes that one of ordinary skill in the art understood the relationship between

(a) the size and distribution of the pores in the microporous film, and

(b) the OTR and R ratio of a membrane produced by coating that microporous film with a polymer.

The Examiner has not provided any reason or evidence that such understanding existed before the present invention. Still less has the Examiner provided any reason or evidence that one of ordinary skill in the art would have found it obvious to make use of a microporous film meeting the specific pore size and distribution requirements in the rejected claims.

The second of these statements, Statement (4), repeats one of the statements made in support of the rejection under 35 U.S.C. 102 and identified as Statement (1) above. It was noted in the discussion of Statement (1) above that it was not clear (in the context of the rejection of the claims limited by the preparation of the microporous film) that the Examiner was referring to by the "recited properties". However, in the context of the present rejection, it appears that the "recited properties" are the limitations that at least 70% of the pores have a pore size of less than 0.24 micron, less than 20% have a pore size less than 0.014 micron, and at least 80% have a pore size of less than 0.15 micron.

For the reasons previously given, Applicants believe that it is wrong to state that "Antoon teaches that which appears to be identical to that disclosed by the applicant with respect to permeability". Still less is it true to conclude that Antoon inherently discloses "the recited properties".

As noted above, paragraph 6 of the Clarke declaration makes it clear that even if two gas-permeable membranes have identical values of OTR and R ratio, it cannot properly be concluded that the microporous films in the membranes are the same. Under these circumstances, it cannot be correct to conclude that Antoon's microporous films inherently possess the limitations that at least 70% of the pores have a pore size of less than 0.24 micron, less than 20% have a pore size less than 0.014 micron, and at least 80% have a pore size of less than 0.15 micron.

In the interests of completeness, Applicants note that, insofar as Antoon contains any teaching about the pore size and distribution of the microporous films, Antoon teaches away from the limitations in the rejected claims. Thus, col. 3, lines 30-34, of Antoon states

5 *A critical feature for high permeance and high CO₂:O₂ ratio... is that the substrate film, although often much thicker than the coating, should be at least two times (preferably at least 10 times) as permeable as the coating itself.*

and col. 3, lines 60-65, of Antoon states

10 *The preferred microporous membrane is a polypropylene film filled with 50 to 65% of CaCO₃ that is uniaxially oriented because this uniaxially oriented film has narrow elongated pores on the surface that are more readily bridged by an intact silicone membrane.*

The first quoted passages does not refer directly to the pore sizes in the microporous film. But, as noted in paragraph 7 of the Clarke Declaration, since larger pore sizes result in greater permeance, the teaching of this passage is that large pore sizes are better than smaller pore sizes. This is, of course, the reverse of Applicants' teaching. The second quoted passage points to the desirability of "narrow elongated pores" when using films containing polypropylene as the polymer and CaCO₃ as the filler, but says nothing about the size of the pores.

20 Applicants recognize that, even though Antoon does not explicitly disclose the pore size and distribution characteristics of claim 20, claim 20 would nonetheless be anticipated if it was shown that a gas-permeable membrane disclosed in Antoon was based on a microporous film which did in fact have the defined pore size and distribution characteristics (and also fulfilled the other requirements of claim 20). The Examiner has not pointed to any reason or evidence that Antoon's microporous films do inherently possess such characteristics. The Clarke declaration makes it clear, in its discussion of the characteristics of voids produced by Antoon's process, that Antoon's microporous films will not possess such characteristics. There is no basis, therefore, for
30 rejecting claim 20 on the basis of inherency.

However, in the interests of completeness, Applicants have made a bona fide attempt to locate and to measure directly the pore size and distribution characteristics of a microporous film made by Antoon's process.

5 So far as Applicants are aware, it is no longer possible to obtain microporous films made by Antoon's drawing process. However, as set out in detail in paragraph 13 of the Clarke Declaration, Applicants have been able to obtain a microporous film which is believed to be a microporous film made by Antoon's drawing process. The microporous film was supplied by Hercules Inc. (Antoon's assignee) to a company
10 called Fresh King Inc. (whose assets were acquired by Apio Inc., now a subsidiary of Landec Corp., the assignees of the present application) for use in the way set out in U.S. Patent No. 4,879,078. The microporous film has been analyzed, and has been shown to be composed of polypropylene having calcium carbonate dispersed therein. The microporous film has also been subjected to mercury porosimetry, and Table C
15 below (which is the same as Table C in paragraph 13 of the Clarke Declaration) sets out the pore size characteristics in relation to the various limitations present in claims 20-23.

Table C

	Claim 20	Fresh King
Average Pore Size (micron)	< 0.24	0.132
% pores < 0.24 micron	> 70%	82 %
% pores < 0.014 micron	< 20%	22%
% pores < 0.15 micron	> 80%	57%
	Claim 21	
% pores < 0.24 micron	> 90%	82 %
	Claim 22	
% pores < 0.24 micron	100%	82%
	Claim 23	
% pores < 0.11 micron	> 70%	40%

20 As noted in the Clarke declaration, Table C makes it clear that the microporous film, although it has an average pore size less than the permitted maximum of 0.24 micron, has many more pores whose size is greater than 0.15 micron than is permitted by the

definition in Claim 20. Additionally, it contains too many relatively large pores to meet the requirements of claims 21-23

Independent Patentability of Claims 21, 22, 23, 31 and 32

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Applicants submit, for the reasons set out below, that the following claims are independently patentable, even if the other claims are unpatentable.

Claim 21. Claim 21 requires that at least 90% of the pores have a pore size less than 0.24 micron. Antoon does not disclose or suggest this feature.

10 Claim 22. Claim 22 requires that substantially 100% of the pores have a pore size less than 0.24 micron. Antoon does not disclose or suggest this feature.

Claim 23. Claim 23 requires that at least 80% of the pores have a pore size less than 0.15 micron and that at least 70% of the pores have a pore size less than 0.11 micron. Antoon does not disclose or suggest this feature.

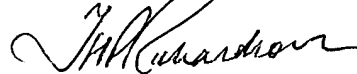
15 Claim 31. Claim 31 requires that the filler in the microporous film is a siliceous filler. Antoon makes it clear that his microporous film must contain 40 to 75% of calcium carbonate. This is explicitly stated in the summary of the invention (col. 2, lines 48-49), in claim 1 (col. 10, lines 9-10) and elsewhere. The Examiner has noted that col. 4, lines 60-67, of Antoon states that "a large number of inorganic materials have been shown to
20 be effective as fillers for effecting void and pore formation", including silica. However, that disclosure is only in the context of a description of "microporous films and the preparation thereof... known in the art" (col. 4, lines 48-49); it is not part of the disclosure of the invention. The likely explanation (and therefore the teaching derived from Antoon by one skilled in the art) for Antoon's explicit choice of calcium carbonate is that
25 microporous films using other fillers are not satisfactory.

Claim 32 Claim 32, which is dependent on claim 31, requires that the polymeric matrix of the microporous film is composed of polyethylene and that the distribution of pore size is as set out in the table forming part of the claim. Thus, claim 32 is
30 substantially restricted to membranes in which the microporous film is the product sold as Teslin SP7, as disclosed on page 17, lines 14-23.

CONCLUSION

5 It is believed that this application is now in condition for allowance, and such action at an early date is earnestly requested. If, however, there are any outstanding issues that could usefully be discussed by telephone, the Examiner is asked to call the undersigned.

Respectfully submitted,



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